

Claims

1. A process for forming a medical device comprising:
 - a) preparing a solid shape-form of a fluidizable composition to define a surface of the device,
 - 5 b) depositing a layer of a curable composition on the shape-form,
 - c) curing at least a portion of the deposited curable composition, and
 - d) removing the shape-form by fluidizing the shape-form material to provide at least a portion of the device composed of the cured composition.
- 10 2. A process as in claim 1 wherein the fluidizable composition is fluidizable by melting under conditions in which physical integrity of the formed device is maintained.
- 15 3. A process as in claim 1 wherein the fluidizable composition comprises ice or a solid waxy material.
4. A process as in claim 1 wherein the curable composition is photocurable.
5. A process as in claim 5 wherein the layer of curable composition is 20 photocured imagewise.
6. A process as in claim 1 wherein the curable composition is deposited in an imagewise manner on the shape-form.
- 25 7. A process as in claim 1 wherein after said curing step, at least one additional layer of curable composition is deposited on the prior formed cured layer and said additional layer is also cured before the shape-form is fluidized.
8. A process as in claim 7 wherein the curable composition is varied in 30 composition between at least two of said layers.
9. A process as in claim 7 wherein said at least one additional layer is configured to provide the device with at least one chamber adapted to contain a drug

therein.

10. A process as in claim 1 wherein the curable composition is varied in formulation over a portion of the device.

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11. A process as in claim 1 wherein the device is a stent or portion thereof, a catheter shaft or portion thereof, a catheter balloon or an integral catheter balloon and catheter shaft or portion thereof.

- 10 12. A process as in claim 1 wherein the curable composition is deposited by spraying.

13. A process as in claim 1 wherein the curable composition is formed by spraying at least two different curable formulations to form a mixed composition which varies over at least a portion of the device.

14. A process as in claim 1 wherein said curable composition comprises a formulation which is photocurable to form a polyimide or a polyester.

- 20 15. A process as in claim 14 wherein the curable composition comprises at least one aromatic 2,5-dialkyl-1,4-diketone and at least one compound having two or more (meth)acrylate or maleimide groups thereon

16. A process as in claim 1 wherein the shape-form is made of material having a melting point of 100°C or less.

- 25 17. A process as in claim 1 wherein the curable composition is deposited uniformly over the surface of the shape-form.

- 30 18. A process as in claim 1 wherein the curable composition is cured by irradiation with light energy, at least a portion of which has a wavelength within the range of from about 400 to about 150 nanometer.

19. A process as in claim 1 wherein the fluidizable composition is fluidizable by dissolution in a solvent which does not substantially attack the cured curable composition.

5 20. A process as in claim 19 wherein the solvent is water.

21. A process as in claim 20 wherein the fluidizable composition comprises a thermoplastic polyvinyl alcohol.

10 22. A medical device formed by a process as in claim 1.

23. A medical device as in claim 22 wherein said curable composition is cured at a temperature below 50°C.

15 24. A medical device formed by a process as in claim 7.

25. A medical device at least a portion of which is formed of a polyimide, polyester, or polyamide produced by photocuring a composition comprising at least one aromatic 2,5-dialkyl-1,4-diketone and at least one compound having two or more 20 maleimide, (meth)acrylate, or (meth)acrylamide groups thereon.

26. A medical device as in claim 25 wherein the device is a stent, a catheter shaft or portion thereof, a catheter balloon or an integral catheter balloon and catheter shaft or portion thereof.

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27. A medical balloon having a longitudinal axis and proximal and distal ends, the balloon formed of polymer material, the balloon connecting to a coaxial shaft at the proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof, and having a central body wall portion between each end spaced apart 30 from the balloon ends and connected thereto by means of tapering proximal and distal wall portions, respectively, wherein the balloon further comprises a lumen extending longitudinally therethrough, said lumen passing through the proximal and distal wall portions of the balloon.

28. A balloon as in claim 27 formed by a process comprising:
- a) preparing a solid balloon-form of a fluidizable composition to define a surface of the device,
 - 5 b) depositing a layer of a curable composition on the balloon-form,
 - c) curing at least a portion of the deposited curable composition, and
 - d) removing the balloon-form by fluidizing the balloon-form material to provide at least a portion of the device composed of the cured composition.
- 10 29. A balloon as in claim 27 wherein the curable composition is a radiation polymerizable composition.
30. A rapid exchange catheter comprising a balloon as in claim 27.
- 15 31. An assembly comprising a rapid exchange catheter as in claim 30 having a stent mounted over the balloon thereof.
32. An article comprising a multi-layer polymeric material film comprising at least first and second layers said first and second layers being in adherent contact with 20 each other over a coextensive area along respective outer and inner surfaces, each of said first and second layers having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface.
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33. An article as in claim 32 wherein said article is a medical device.
34. An article as in claim 32 wherein said article is a dilatation balloon and said film is the balloon wall.
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35. A dilatation balloon as in claim 34 wherein said balloon wall has generally coplanar inner and outer surfaces, said coextensive area is a region between, and generally coplanar with, the inner and outer balloon wall surfaces.

36. A dilatation balloon as in claim 35 wherein said coextensive area is a region which extends over less than the entire the balloon wall.

5 37. A dilation balloon as in claim 36 wherein one of said layers is an elastomeric band which has been stretched from an at rest configuration prior to inclusion thereof within the balloon wall.

10 38. A dilatation balloon as in claim 35 wherein said coextensive area extends over substantially the entire balloon wall.

39. A process for forming an article comprising:

- a) preparing a solid shape-form of a fluidizable composition to define a surface of the device,
- 15 b) depositing a layer of a radiation curable composition on the shape-form,
- c) curing at least a portion of the deposited radiation curable composition by irradiation, and
- d) removing the shape-form by fluidizing the shape-form material to provide at least a portion of the article composed of the photocured composition.

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40. A process as in claim 39 wherein the radiation curable composition is photocurable with light energy in the range of from about 400 nm to about 150 nm.

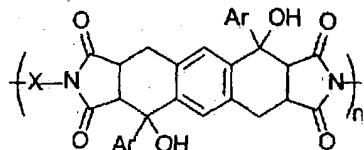
25 41. A process as in claim 40 wherein the curable composition is photocurable to form a polyimide, polyester or polyamide.

42. A process as in claim 40 wherein the curable composition comprises at least one aromatic 2,5-dialkyl-1,4-diketone and at least one compound having two or more maleimide, (meth)acrylate, or (meth)acrylamide groups thereon.

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43. A process as in claim 41 wherein the photocurable composition comprises at least one compound having two or more maleimide groups thereon.

44. A process as in claim 43 wherein the photocured composition is a polymer of the general formula:



5 where X is a carbon-linked organo group, Ar is an optionally substituted aromatic moiety and n is a positive number.

45. A process as in claim 39 wherein the curable composition is varied in formulation over a portion of the article.

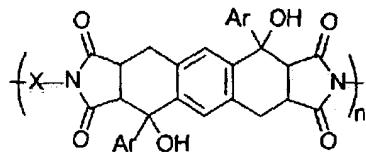
10 46. A process for forming an article comprising
a) preparing a solid shape-form of ice to define a surface of the device,
b) depositing a layer of a curable composition on the ice shape-form,
c) curing at least a portion of the deposited curable composition, and
d) removing the shape-form by melting the ice to provide at least a portion of the
15 article composed of the cured composition.

47. A process as in claim 46 wherein the curable composition is varied in formulation over a portion of the article.

20 49. A process for forming an article comprising
a) preparing a solid shape-form of a fluidizable composition to define a surface of the device,
b) depositing a layer of a curable composition on the shape-form, wherein the curable composition is varied in formulation over a portion of the article,
25 c) curing at least a portion of the deposited curable composition, and
d) removing the shape-form by fluidizing the shape-form material to provide at least a portion of the article composed of the cured composition.

50. A medical device formed of a polyimide material, said polyimide material obtained by curing a polyimide-forming composition at a temperature of 50°C or less.

5 51. A medical device as in claim 50 wherein the polyimide material is a polymer of the general formula:



where X is a carbon-linked organo group, Ar is an optionally substituted aromatic moiety and n is a positive number.

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52. A medical device as in claim 50 wherein polyimide-forming composition is curable by irradiation with light energy in the range of from about 400 nm to about 150 nm.

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53. A mold form for a medical device or portion thereof, said device being formed directly on the mold form, wherein the form is made of a material which is fluidizable at a temperature of 100°C or less.

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54. A mold form as in claim 53 wherein said material is fluidizable at a temperature of 50°C or less.

55. A mold form as in claim 53 wherein said material is fluidizable by melting at a temperature of 100°C or less.

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56. A mold form as in claim 53 wherein said material is fluidizable by melting at a temperature of 50°C or less.

57. A mold form as in claim 53 wherein said material is ice.

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58. A mold form as in claim 53 wherein said material is wax.

59. A mold form as in claim 53 wherein said material is fluidizable by dissolution in water or an organic solvent.

5 60. A mold form as in claim 59 wherein said material comprises polyvinylalcohol.

61. A mold form as in claim 53 having embedded therein a support structure which is non-fluidizable under conditions which fluidize the form material, but is removable from a formed device after the form has been fluidized.

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62. A mold form as in claim 53 defining a device volume adjacent thereto, the mold form having embedded therein a plurality of fibers which are non-fluidizable under conditions which fluidize the form material, and which project into the device volume so that when the device has been formed on the mold form and the mold form has been fluidized, the fibers become incorporated into the device structure.

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63. A mold form as in claim 53 for forming a catheter, a stent, a catheter balloon, or a portion thereof.